NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., Plaintiff, v. SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, ODIN PHARMACEUTICALS, LLC, RK PHARMA, INC., APOTEX CORP., APOTEX, INC., and ACCORD HEALTHCARE, INC., Defendants.	Case No. 2:24-cv-01022 (BRM) (CLW) **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before this Court is Plaintiff American Regent, Inc.'s ("ARI") Motion to Dismiss the Counterclaims of Defendant RK Pharma, Inc. ("RK Pharma") (ECF No. 91) for failure to state a claim on which relief may be granted, and to strike RK Pharma's related defenses (ECF No. 102 (the "Motion")). RK Pharma opposed the Motion (ECF No. 103), and ARI filed a reply (ECF No. 4). Having reviewed and considered the submissions filed in connection with the Motion and having declined to hold oral argument pursuant to Federal Rule of Civil Procedure 78(b), for the reasons set forth below and for good cause having been shown, ARI's Motion to Dismiss the Counterclaims and to Strike is **GRANTED IN PART AND DENIED IN PART**.

I. BACKGROUND

A. Factual Background

The underlying litigation relates to several patents owned by ARI that RK Pharma and other generic drug manufacturers ("Defendants") seek to challenge. ARI is a pharmaceutical

corporation with a principal place of business in New York State. (ECF No. 88 ¶ 2.) ARI has several patents—United States Patent Nos. 11,786,548 (the "'548 Patent"), 11,975,022 (the "'022 Patent"), 11,998,565 (the "'565 Patent"), 12,150,956 (the "'956 Patent"), and 12,150,957 (the "'957 Patent") (collectively, the "patents-in-suit")—as well as New Drug Applications ("NDAs") from the Food and Drug Administration ("FDA") for two multi-trace element injection products, Tralement and Multrys. (*Id.* ¶¶ 1, 26–27, 35–42.) The patents-in-suit and the related products are directed to providing parenteral, *i.e.*, intravenous, nutrition to patients who cannot adequately absorb nutrients through the digestive tract. (ECF No. 111 at 4.) Both products contain multiple trace elements, or elements necessary to certain human metabolic functions at relatively low levels. (*Id.*) ARI's Tralement and Multrys include trace elements such as zinc, copper, manganese, and selenium. (*Id.*) These products are the first FDA-approved multi-trace element injections, Tralement for patients weighing at least 10 kg, and Multrys for neonatal and pediatric patients weighing under 10 kg. (ECF No. 88 ¶¶ 22, 24.)

Defendants are generic pharmaceutical companies that have submitted Abbreviated New Drug Applications ("ANDAs") to the FDA, seeking approval to sell generic versions of Tralement and Multrys in the United States (the "ANDA Products"). (ECF No. 88 ¶¶ 1, 11.) The underlying litigation relates to ARI's attempts to prevent the market entry of Defendants' ANDA Products. Like the other Defendants, ARI alleges RK Pharma seeks to infringe the patents-in-suit, and asks the Court to make findings of infringement, enjoin RK Pharma manufacturing or selling the ANDA Products until the expiration of the patents-in-suit, and award monetary damages and attorneys' fees. (*Id.* ¶¶ 49–79, Prayer for Relief.)

B. Procedural History

ARI sued Defendants between February 22, 2024, and March 11, 2024. (ECF No. 1; Civ. A. No. 2:24-01169, ECF No.1; Civ. A. No. 2:24-02268, ECF No. 1.) On June 12, 2024, ARI's suits were consolidated into this action. (ECF No. 37.) Thereafter, ARI filed First Amended Complaints against Defendants on June 20, 2024 (ECF Nos. 41–44), and Second Amended Complaints on January 3, 2025 (ECF Nos. 85–88). Defendants filed their respective Answers and counterclaims to the Second Amended Complaints on January 24, 2025. (ECF Nos. 91–94.) On November 8, 2024, ARI initially moved to dismiss RK Pharma's counterclaims in its Answer to the First Amended Complaint. (ECF No. 75.) When ARI filed the Second Amended Complaints and RK Pharma filed its amended Answer and counterclaims, ARI renewed its motion to dismiss on February 25, 2025. (ECF No. 102.) RK Pharma filed its opposition on February 26, 2025 (ECF No. 103), and ARI replied on February 27, 2025 (ECF No. 104).[1]

Subsequently, ARI and all Defendants (including RK Pharma) filed a Joint Claim Construction and Prehearing Statement on April 4, 2025 (ECF No. 110), and their respective opening briefs on April 18, 2025 (ECF Nos. 111, 112). The parties filed responsive briefs on May 7, 2025 (ECF Nos. 113, 114), and the Court held oral argument on claim construction on June 12, 2025 (ECF No. 125). The questions of claim construction addressed in those briefings and oral argument remains pending before the Court.

[1] ARI initially filed a motion to dismiss RK Pharma's counterclaims in its Answer to the First Amended Complaint, which was fully briefed. (ECF Nos. 75, 78, 83.) Following the filing of RK Pharma's Second Amended Complaint and the corresponding Answer, the Court instructed the parties to refile their respective briefings to reflect changes in the pagination of the Second Amended Complaint and the Answer and counterclaims. (ECF No. 98.)

C. RK Pharma's Answer, Defenses and Counterclaims

On a motion to dismiss, the Court accepts the factual allegations in RK Pharma's counterclaims as true and draws all inferences in the light most favorable to it. *See Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). The Court also considers any "document integral to or explicitly relied upon in the complaint" (here, the counterclaim allegations). *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (quoting *Shaw v. Digit. Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996)).

In its counterclaims, RK Pharma seeks "a declaratory judgment of non-infringement and/or unenforceability of the claims of" the patents-in-suit. (ECF No. 91 ¶ 2.) RK Pharma alleges ARI obtained two of the patents-in-suit, the '548 and '022 Patents (which share "substantively identical" specifications (*id.* ¶¶ 39, 163)) through inequitable conduct "including intent to deceive the [U.S. Patent and Trademark Office ("USPTO")] by the named inventors, prosecuting attorneys, agents or firm, declarants, Plaintiff/Counterclaim-Defendant American Regent, Inc., and/or any other party or parties substantially involved in the prosecution of the '548 patent (collectively, 'the applicants')" (*id.* ¶¶ 36, 163–69). RK Pharma presents four theories of how "the applicants'" prosecution of the '548 Patent constituted inequitable conduct, all of which it contends apply to the '022 Patent as well. (*Id.* ¶¶ 76–148, 159–69.) Based on these alleged behaviors, RK Pharma contends "[t]he most reasonable inference is that the applicants" sought to protect ARI's exclusivity rights to Tralement and Multrys, which were already on the market, from ANDA filers like Defendants and set out to deceive the patent examiner into issuing patents covering those products, so that ARI would be entitled to preemptively sue for patent infringement and to obtain a 30-month stay under the Hatch-Waxman Act. (*Id.* ¶ 148.)

First, RK Pharma alleges the applicants aimed to "bury" material prior art by submitting "about 8 separate information disclosure statements (IDSs)" to the USPTO during the prosecution of the '548 Patent (the "burying theory"). (*Id.* ¶¶ 76.) RK Pharma alleges these IDSs were filed by William D. Schmidt ("Schmidt"), who also submitted the application (the "'695 Application") that became the '548 Patent. (*Id.* ¶¶ 48, 76.) RK Pharma claims the total file history comprises more than 8,000 pages, and none of the non-patent literature submitted (over 200 references, some of which were provided only in abstract form) was provided "in PDF/Optical Character Recognition (OCR) form that would allow word-searching of the text of the PDF." (*Id.* ¶¶ 77–80.) As a result, the volume of materials essentially rendered it impossible for the patent examiner to "determin[e] the materiality of a reference." (*Id.* ¶ 82.) RK Pharma alleges ways in which "[a]pplicants and/or their attorney William D. Schmidt" could have aided the patent examiner's task (but did not), such as by providing OCR-searchable references in full-text form, organizing the references to enable the examiner's review, or "including a statement of relevance" for each reference. (*Id.* ¶¶ 81–86.) Instead, RK Pharma alleges "the applicants and their attorney William D. Schmidt intentionally 'buried' the examiner under many references" to hide "highly material prior art references" amongst mostly "insignificant" ones. (*Id.* ¶¶ 87–88.) RK Pharma specifically highlights a reference to "Olson, Logan M. et al., *Quantitative Assessment of Trace Element Contamination in Parenteral Nutrition Components*, Journal of Parenteral and Enteral Nutrition. Vol. 43, Issue No. 8, Nov 2019. ABSTRACT" ("Olson 2019"), which it contends would have "contradicted the basis for allowance" of the '548 Patent through its teachings about chromium contamination in parenteral nutrition products and its suggestion to study other potential sources of contamination in the production processes. (*Id.* ¶¶ 89–91.) Therefore, RK Pharma alleges "the applicant[s] and their attorney William D. Schmid[t]" intended to deceive the USPTO by burying the Olson 2019

reference, violating their obligation of candor and good faith to the USPTO, and the '548 and '022 Patents would not otherwise have been issued. (*Id.* ¶¶ 92–95, 169.)

RK Pharma's second and third theories relate to the declaration of Dr. Joseph I. Boullata ("Dr. Boullata") (the "Boullata Declaration") in the '695 Application. (*Id.* ¶¶ 96–121.) First, RK Pharma alleges the Boullata Declaration cherry-picked quotes from a particular reference, the "ASPEN Guidelines," in order make it appear the '695 Application filled a need in the field regarding proper parenteral nutrition doses of chromium and selenium, which RK Pharma contends was already known in the art (the "cherry-picking theory"). (*Id.* ¶¶ 108–11.) RK Pharma therefore alleges "the applicants and William D. Schmidt acted with deceptive intent during the prosecution of" the '695 Application by allowing the patent examiner to rely on the information conveyed in the Boullata Declaration as "unbiased [and] truthful," without which RK Pharma contends the '548 Patent would not have issued. (*Id.* ¶¶ 112–14.) Second, RK Pharma alleges Dr. Boullata "was a consultant and speaker for" ARI during the '548 Patent's prosecution, yet "the applicants failed to disclose [this relationship] to the examiner," information which also would have colored the patent examiner's understanding of the '695 Application and would have prevented its issuance (the "undisclosed relationship theory"). (*Id.* 115–21.)

Lastly, RK Pharma attacks the declaration of Dr. Roshan James ("Dr. James") (the "James Declaration"), submitted following discussions with the patent examiner, which provided "comparative data showing unexpectedly reduced elemental impurities of" ARI's parenteral nutrition products covered by the '548 Patent. (*Id.* ¶ 122.) The James Declaration reports data finding Tralement had lower concentrations of silicon than competitor multi-trace element products, and Tralement and Multrys had lower concentrations of bacteria endotoxins. (*Id.* ¶¶ 123–32.) However, RK Pharma alleges the data presented show only one round of comparative testing

between ARI's products and competitors, and the James Declaration does not report the standard error of the measurements from any testing, meaning "there is no guarantee that these results are even statistically significant." (*Id.* ¶¶ 133–34.) RK Pharma therefore alleges the testing reported in the James Declaration is not reliable, and the testing should have followed "a more comprehensive process." (*Id.* ¶¶ 135–41.) RK Pharma claims "the incomplete and misleading [testing and reporting] process was intentional in order to obtain allowance of the claims of the patent" by "Dr. James and William D. Schmidt, who submitted the [James] Declaration." (*Id.* ¶ 142.) RK Pharma alleges "Dr. James, the applicants, and William D. Schmidt" knowingly provided this misleading information to the USPTO to deceive the patent examiner and obtain the '548 Patent (the "misleading data theory"). (*Id.* ¶¶ 143–46.) Finally, RK Pharma alleges the '548 Patent would not have issued but for the patent examiner's consideration of the James Declaration's data. (*Id.* ¶ 146.)

II. LEGAL STANDARD

A. Motion to Dismiss

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is "required to accept as true all factual allegations in the complaint and draw all inferences from the facts alleged in the light most favorable to [the non-moving party]." *Phillips*, 515 F.3d at 228. "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). However, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 555 (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those "[f]actual

allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*, 550 U.S. at 556). This "plausibility standard" requires the complaint to allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a 'probability requirement.'" *Id.* (citing *Twombly*, 550 U.S. at 556). "Detailed factual allegations" are not required, but "more than an unadorned, the-defendant-unlawfully-harmed-me accusation" must be pled; it must include "factual enhancements" and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citations omitted). In assessing plausibility, the court may not consider any "[f]actual claims and assertions raised by a defendant." *Doe v. Princeton Univ.*, 30 F.4th 335, 345 (3d Cir. 2022).

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (quoting Fed. R. Civ. P. 8(a)(2)). Indeed, after *Iqbal*, conclusory or "bare-bones" allegations will no longer survive a motion to dismiss: "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678. To prevent dismissal, all civil complaints must set out

"sufficient factual matter" to show that the claim is facially plausible, allowing "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* The Supreme Court's ruling in *Iqbal* emphasizes that a plaintiff must show that the allegations of his or her complaints are plausible. *See id.* at 670.

While, generally, the court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to Rule 12(b)(6), the Third Circuit has held that "a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant to Rule 56]." *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any "document *integral to or explicitly relied* upon in the complaint." *In re Burlington Coat Factory*, 114 F.3d at 1426 (emphasis added) (quoting *Shaw*, 82 F.3d at 1220). However, "[w]hen the truth of facts in an 'integral' document are contested by the well-pleaded facts of a complaint, the facts in the complaint must prevail." *Princeton Univ.*, 30 F.4th at 342.

B. Motion to Strike

A court may, upon motion or *sua sponte*, "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "The purpose of a motion to strike is to simplify the pleadings and save time and expense by excising from a plaintiff's complaint any redundant, immaterial, impertinent, or scandalous matter which will not have any possible bearing on the outcome of the litigation." *Garlanger v. Verbeke*, 223 F. Supp. 2d 596, 609 (D.N.J. 2002) (internal quotations omitted). However, "[b]ecause of the drastic nature of the remedy, . . . motions to strike are usually 'viewed with disfavor' and will generally 'be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues.'" *Id.* (citing *Tonka Corp. v. Rose Art Indus.,*

Inc., 836 F. Supp. 200, 217 (D.N.J. 1993)); *see also Weske v. Samsung Elecs., Am., Inc.*, 934 F. Supp. 2d 698, 702 (D.N.J. 2013) (explaining motions to strike are extremely disfavored). "A court possesses considerable discretion in disposing of a motion to strike under Rule 12(f)." *Kim v. Baik*, Civ. A. No. 06-3604, 2007 WL 674715, at *5 (D.N.J. Feb. 27, 2007).

III. DECISION

ARI asks the Court to dismiss RK Pharma's inequitable conduct counterclaims on several grounds. (ECF No. 102 at 20–40.) First, ARI contends none of RK Pharma's allegations meet the heightened pleading standard imposed by Federal Rule of Civil Procedure 9 ("Rule 9") because they do not properly plead "who" committed material omissions or misrepresentations. (*Id.* at 20–23.) Next, ARI argues RK Pharma's burying theory is deficient because: (1) its allegations fail to show the Olson 2019 reference was in fact buried; (2) the counterclaims fail to allege any burying of Olson 2019 was material; and (3) RK Pharma did not plausibly allege an intent to bury the reference. (*Id.* at 23–32.) Similarly, ARI asserts RK Pharma's "cherry[-]picking theory" does not contain sufficient allegations of materiality or intent to support a finding of inequitable conduct. (*Id.* at 32–36.) ARI also argues RK Pharma fails to allege Dr. Boullata's relationship to ARI was concealed, and any failure to adequately disclose the nature of the relationship was neither intentional nor constituted a but-for material omission. (*Id.* at 36–38.) Finally, ARI contends RK Pharma's allegations of a misrepresentation in the James Declaration fail to identify a false statement that would constitute fraud. (*Id.* at 38–40.)

In evaluating the sufficiency of a counterclaim, district courts must separate the factual and legal elements. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 210–11 (3d Cir. 2009). A court "must accept all of the [counterclaim]'s well-pleaded facts as true" and give a defendant the benefit of all reasonable inferences flowing therefrom. *Id.* at 210. A court, however, does not credit labels,

conclusions, or a formulaic recitation of the elements of a cause of action. *See Twombly*, 550 U.S. at 555. Furthermore, while pleading standards in patent cases generally apply the law of the applicable circuit, courts apply the law of the Federal Circuit in assessing whether a claim of inequitable conduct has been properly pled under Federal Rules of Civil Procedure, as it is a question of patent law. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326–27 (Fed. Cir. 2009); *see also Novartis Pharms. Corp. v. Roxane Lab'ys, Inc.*, 2011 WL 1322271, at *7 (D.N.J. Mar. 31, 2011); *Eagle View Techs., Inc. v. Xactware Sols., Inc.*, 325 F.R.D. 90, 93 (D.N.J. 2018) ("Determining sufficiency of a motion pleading inequitable conduct before the PTO is a question of patent law and, as such, governed by Federal Circuit law.").

A. Rule 9 Pleading Sufficiency

ARI argues all RK Pharma's allegations lack the specificity required by Rule 9(b) because they fail to allege "any specific individual associated with the prosecution both knew of any material information and deliberately withheld, misrepresented, or 'buried' it." (*Id.* at 20.) ARI contends the Federal Circuit reads Rule 9(b) to require identifying a specific individual who had a duty of candor to the USPTO for an inequitable conduct claim. (*Id.* at 21 (citing *Exergen*, 575 F.3d at 1329).) Because RK Pharma repeatedly alleges the purportedly inequitable conduct was undertaken by "the applicants," a broad term encompassing "the named inventors, prosecuting attorneys, agents or firm, declarants, . . . [ARI], and/or any other party or parties substantially involved in the prosecution of the patent-in-suit," ARI contends it cannot state an equitable conduct claim with the particularity required. (*Id.* at 21–23.) ARI asserts "it is well-established" corporate entities cannot commit inequitable conduct offenses, so RK Pharma's allegations as to ARI itself fail as a matter of law. (*Id.* at 21 (citing *Exergen*, 575 F.3d at 1329).) Additionally, ARI argues the repeated references to "the applicants" "effectively try to impute the knowledge of an entire

corporation to everyone associated with the prosecution" and are similarly deficient. (*Id.* at 21–22.) While acknowledging RK Pharma amended its counterclaims to allege "the applicants and/or their attorney" committed deceptive acts, ARI contends this has no corrective effect because: (1) "the applicants" was already defined to include ARI's prosecuting attorneys; and (2) courts in the Third and Federal Circuits have rejected similar pleading formulations. (*Id.* at 22–23 (citing *Exergen*, 575 F.3d at 1329; *Senju Pharma Co., Ltd v. Apotex, Inc.,* 921 F. Supp. 2d 297, 307 (D. Del. 2013); *Catalyst Pharm., Inc. v. Jacobus Pharm. Co.,* No. 3:20-14590, ECF No. 121 at 11 (D.N.J. May 26, 2022)).)

RK Pharma asserts it has adequately pled the "who" required by Rule 9(b) because it alleged several individuals—Schmidt, Dr. Boullata, and Dr. James—took specific intentional and misleading acts. (ECF No. 103 at 11–12.) In RK Pharma's view, the allegations adequately state: (1) Schmidt submitted the excessive IDSs to the USPTO in order to "bury" Olson 2019, helped present the misleading information in the Boullata and James Declarations, and helped conceal Dr. Boullata's relationship with ARI; (2) Dr. Boullata presented information in his Declaration that lead to misleading and/or false conclusions; (3) and Dr. James provided "improper testing data and misleading conclusions." (*Id.*) In response to ARI's assertion the repeated references to "the applicants" render the allegations deficient, RK Pharma argues these statements "do not negate the specific allegations against individuals, but serve the purpose of describing the events fully" and providing notice to those involved in ARI's "overall scheme." (*Id.* at 12–13.) Moreover, RK Pharma contends the Federal Circuit permits findings of inequitable conduct "based on the actions of multiple individuals," including "unnamed individuals in a company" and the corporate entity itself. (*Id.* at 13–14 (citing *GS CleanTech Corp. v. Adkins Energy LLC*, 951 F.3d 1310, 1316–29 (Fed. Cir. 2020)).)

In reply, ARI refutes that naming Schmidt, Dr. Boullata, and Dr. James satisfies Rule 9(b) and the Federal Circuit's guidance. (ECF No. 14 at 4–5.) ARI asserts RK Pharma "must provide some factual basis to conclude that a specific individual materially misled the [USPTO] and did so intentionally" but instead makes "[a]morphous allegations" against "a large group of named and unnamed people." (*Id.*) In response to RK Pharma's argument the allegations referencing "the applicants" provide notice to those involved in the overall scheme, ARI contends this amounts to "indiscriminately accus[ing] and/or absolv[ing]" all those involved, "exactly the type of pleading Rule 9(b) was designed to prevent." (*Id.* at 5 (quoting *Webasto Thermo & Comfort N. Am., Inc. v. Bestop, Inc.*, 326 F. Supp. 3d 521, 530 (E.D. Mich. 2018)).) Finally, ARI argues RK Pharma's citation to *CleanTech* is both inapposite, as it involved inequitable conduct findings after a bench trial and did not speak to the "who" required by Rule 9(b), and also misguided, as ARI contends "the underlying finding of inequitable conduct" did not apply to the corporate owner of the patent. (*Id.* at 5–6 (citing *CleanTech*, 951 F.3d at 1315, 1326–29).)

"The substantive elements of inequitable conduct are: (1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO." *Exergen*, 575 F.3d at 1327 n.3. While a broader concept, inequitable conduct sounds in fraud and therefore must be pled with particularity under Rule 9(b). *Id.* at 1326–27. The Federal Circuit has explained particularity "requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Id.* at 1327. Putting these requirements together, allegations of inequitable conduct must allow the court to "reasonably infer that *a specific individual* (1) knew of the withheld material information or of the falsity of the material

misrepresentation, *and* (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 1329 (emphases added); *see also Eagle View,* 325 F.R.D. at 94 ("The 'who' must be pled with the name of the person who withheld or misrepresented the information."). While *Exergen* addressed a motion to amend following a trial on the merits, "courts in this District have held that *Exergen* applies to the pleading stage." *Fresenius Kabi USA, LLC v. Fera Pharms., LLC*, Civ. A. No. 15-3654, 2016 WL 5348866, at *10 (D.N.J. Sept. 23, 2016).

In *Exergen*, the Federal Circuit found allegations "Exergen was aware" of the materiality of prior art, and "Exergen, its agents and/or attorneys intentionally withheld" the prior art did not meet the Rule 9(b) standard because they failed to name a "specific individual associated with the filing or prosecution of the [patent] who both knew of the material information and deliberately withheld or misrepresented it." 575 F.3d at 1325, 1329. Citing to the USPTO regulations and Manual of Patent Examining Procedures' ("MPEP") guidance that only specific individuals have duties of candor and good faith to the USPTO, the Federal Circuit indicated allegations of inequitable conduct against an organization are insufficient. *See id.* at 1329. Decisions following *Exergen* have explicitly held this to be the case. *See, e.g.*, *Int'l Bus. Machs. Corp. v. Priceline Grp. Inc.* ("*IBM*"), Civ. A. No. 15-137, 2017 WL 1349175, at *8 (D. Del. Apr. 10, 2017) ("[T]he law is clear that 'only individuals, rather than corporations . . . owe a duty of candor to the PTO.'" (quoting *Avid Identification Sys., Inc. v. Crystal Imp. Corp.*, 603 F.3d 967, 974 n.1 (Fed. Cir. 2010)), *report and recommendation adopted sub nom.*, *Int'l Bus. Machs. Corp. v. The Priceline Grp. Inc.*, Civ. A. No. 15-137, 2017 WL 11549735 (D. Del. May 10, 2017); *Senju*, 921 F. Supp. 2d at 307 ("As in *Exergen,* Apotex's inclusion of general entities . . . in the pleadings does not permit the court to reasonably infer that any specific individual was responsible."); *Inst. for Env't Health, Inc. v. Nat'l Beef Packing Co., LLC*, Civ. A. No. 23-826, 2024 WL 5117412, at *6 (D. Del. Dec.

16, 2024) ("[I]dentifying a corporation, rather than an individual, as the 'who' is not enough to satisfy this requirement [of Rule 9(b)]."). To the extent RK Pharma alleges ARI as an entity engaged in inequitable conduct, such claims fail on this basis. However, RK Pharma's counterclaims contain a mix of allegations against "the applicants," "the applicants and[/or] their attorney William D. Schmidt," and specific individuals (Schmidt, Dr. Boullata, and Dr. James), which require further scrutiny.

When assessing whether the "who" of an inequitable conduct claim is present, courts have generally rejected pleadings referring to unnamed groups or individuals, instead requiring the members of any referenced group to be clearly ascertainable. *Compare Telebrands Corp. v. 1byOne Prods., Inc.*, Civ. A. No. 17-997, 2018 WL 3696558, at *2 (D. Del. Aug. 3, 2018) ("The pleading does not adequately identify the 'who' of the misrepresentation because it generally refers to the 'named inventors.'"); *Senju*, 921 F. Supp. 2d at 307 (rejecting pleading "inventors and/or those acting on their behalf" engaged in inequitable conduct because the "broadly cast net around the inventors and those acting on their behalf . . . does not allow the court to reasonably infer that a specific individual both knew of the invalidating information and had a specific intent to deceive the PTO"); *and Inst. for Env't Health*, 2024 WL 5117412 at *7 (finding allegations patentee's attorneys "omitted material information" did not meet Rule 9(b)), *with Depomed, Inc. v. Purdue Pharma L.P.*, Civ. A. No. 13-571, 2017 WL 2804953, at *6 (D.N.J. June 28, 2017) (determining pleading requirements met where counterclaimant alleged counterclaim defendant's "counsel and Inventor Helm" knew material information was false and intended to deceive USPTO); *and Diebold Nixdorf, Inc. v. Hyosung Tns, Inc.*, Civ. A. No. 19-1695, 2021 WL 861734, at *3 (D. Del. Mar. 4, 2021) (finding "who" requirement met because "Defendants list a group of inventors by name and allege that each one of the group of individuals engaged in inequitable conduct"); *accord*

IBM, 2017 WL 1349175, at *9 (noting groups like "named inventors" or "prosecuting attorneys" "*could* be specific enough to meet the 'who' requirement, to the extent that they could be understood to accuse each of the members of a known, clearly ascertainable group").

Courts also reject allegations against named individuals "and/or" other persons or groups because they fail to denote "exactly which individual or individuals [had] knowledge of the material information and . . . had a deliberate intent to deceive." *Invista N. Am. S.a.r.l. v. M&G USA Corp.*, Civ. A. No. 11-1007, 2013 WL 12304544, at *8 (D. Del. May 3, 2013); *see also XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 381 (D. Del. 2012) (finding allegations "either Zelkin, or 'one or more' of the other inventors, knew about the prior sales and art and their materiality" failed Rule 9(b) standard); *LEO Pharma A/S v. Actavis Lab'ys UT, Inc.*, Civ. A. No. 16-333, 2018 WL 1045816, at *4 (D. Del. Feb. 26, 2018) (determining broad allegations named inventors, patent attorneys or agents, "and / or" counterclaim defendant employees "leave open the possibility that the counterclaim 'implicate[s] all or none of the individuals who had dealings with the PTO'" and lack particularity (quoting *Senju*, 921 F. Supp. 2d at 307)); *see also Mitsubishi Heavy Indus., Ltd. v. Gen. Elec. Co.*, Civ. A. No. 6:10-812, 2012 WL 831525, at *2 (M.D. Fla. Mar. 12, 2012) ("Through the 'and' part of the [and/or] conjunction, GE has managed to lump the named inventors, attorneys, and agents together . . . , and through the 'or' portion GE has disjoined them; the result is that GE has failed to specifically identify who is guilty of misconduct.").

Additionally, inequitable conduct allegations must allege the *same* specific individual(s) "both knew of the material information and deliberately withheld or misrepresented it." *Exergen*, 575 F.3d at 1329; *see, e.g.*, *Jazz Pharms. Rsch. UK Ltd. v. Teva Pharms., Inc.*, 711 F. Supp. 3d 244, 253–55 (D.N.J. 2024) (holding intent inadequately pled where allegations named specific individuals who filed misleading patent applications but did not allege they knew information that

rendered applications misleading); *Warner Chilcott Co., LLC v. Amneal Pharms., LLC*, Civ. A. No. 11-5989, 2013 WL 6627694, at *9 (D.N.J. Dec. 20, 2013) (rejecting inequitable conduct pleadings where defendants sufficiently pled named inventor knew of allegedly material information but failed to allege he was "was aware of [its] materiality or that he had the opportunity to disclose it and deliberately decided against it"); *IBM*, 2017 WL 1349175 at *9 (finding Rule 9(b) standard not met for all but one named individual because "there are not sufficient facts pleaded to establish, *inter alia*, that the 'named inventors' or 'prosecuting attorneys' (other than Mr. Scifo) actually had knowledge of the activities that they allegedly failed to disclose").

The *IBM* opinion illustrates many of these principles, 2017 WL 1349175 at *8–9. There, the counterclaim plaintiffs made allegations of inequitable conduct against a bevy of different groups, including "(1) certain unnamed 'individuals at IBM, who will be identified during discovery,' (2) 'IBM [and] and its agents[,]' or 'Trintex[,]' (3) 'prosecuting attorneys[,]' and (4) the 'named inventors.'" *Id.* at *8. The court quickly determined the unnamed individuals at IBM "[could not] serve as the basis for an inequitable conduct counterclaim" because there was no specific individual identified with a duty of candor to the USPTO. *Id.* While the court acknowledged allegations against "a known, clearly ascertainable group" could satisfy Rule 9(b), it found the allegations against the "named inventors" and "prosecuting attorneys" were nonetheless insufficient because they consisted of vague statements "on information and belief," rather than "actual facts . . . that would allow the inference that each of the named inventors [or patent attorneys] had knowledge of the relevant [information]." *Id.* at *9. However, the court found allegations of inequitable conduct by "IBM's prosecuting attorney," Mr. Scifo, could stand because he was "specifically (and repeatedly) identified . . . as an individual who intentionally made material misrepresentations or omissions to the PTO during prosecution." *Id.*

Following the Federal Circuit's approach in *Exergen* as informed by its application in this and other district courts, it is clear RK Pharma's allegations against "the applicants" are too broad to satisfy the "who" of Rule 9(b). This umbrella term, which RK Pharma defines as "the named inventors, prosecuting attorneys, agents or firm, declarants, Plaintiff/Counterclaim-Defendant American Regent, Inc., and/or any other party or parties substantially involved in the prosecution of the '548 patent" (ECF No. 91 ¶ 36), effectively "implicate[s] all or none of the individuals who had dealings with the PTO," not any specific individual. *Senju*, 921 F. Supp. 2d at 307; *see also Invista*, 2013 WL 12304544 at *8. While the "named inventors" are individually identified in the counterclaim allegations (ECF No. 91 ¶ 41), the use of "and/or" within the definition of "the applicants" renders each inventor both included and excluded from allegations as to materiality and intent. *See IBM*, 2017 WL 1349175 at *9; *Mitsubishi Heavy Indus.*, 2012 WL 831525 at *2. So too for the instances where RK Pharma alleges "the applicants *and/or* their attorney William D. Schmidt" failed to take certain actions to surface material prior art, as the "and/or" neither conclusively includes nor excludes Schmidt's involvement. (ECF No. 91 ¶¶ 81–83.); *see also XpertUniverse*, 868 F. Supp. 2d at 381; *Leo Pharma*, 2018 WL 1045816 at *4.

But in other instances, RK Pharma alleges "the applicants *and* their attorney William D. Schmidt" took certain actions or had certain knowledge. (ECF No. 91 ¶¶ 82, 84–89, 92–94, 111–14, 119–21, 143–46.) In the most favorable reading, this phrasing alleges Schmidt had a role in the inequitable conduct. *See IBM*, 2017 WL 1349175 at *9; *Depomed*, 2017 WL 2804953 at *6. With such statements, as well as others describing Schmidt's own actions, RK Pharma sufficiently

alleges he "both knew of the material information and deliberately withheld or misrepresented it" as to all but one of its theories of inequitable conduct.[2] *Exergen*, 575 F.3d at 1329.

RK Pharma's allegations of inequitable conduct by Schmidt fall short for the undisclosed relationship theory because nowhere does RK Pharma allege Schmidt knew of Boullata's role as a consultant for ARI, and Schmidt could not withhold information he did not possess. *See, e.g.*, *Jazz Pharms.*, 711 F. Supp. 3d at 254 (finding knowledge of material information allegedly withheld must be specifically pled under Rule 9(b)). RK Pharma simply states Dr. Boullata "was a consultant and speaker" for ARI, and Schmidt "fail[ed] to disclose" that information; that does not suffice. (ECF No. 91 ¶¶ 115, 121.) As Schmidt is the only specific individual identified as intending to deceive the USPTO as to this relationship, RK Pharma's inequitable conduct claim cannot proceed on this theory.[3] *See Jazz Pharms.*, 711 F. Supp. 3d at 254; *Warner Chilcott*, 2013 WL 6627694 at *9.

As to the inequitable conduct theories surrounding the content of the James and Boullata Declarations, RK Pharma sufficiently identified Drs. James and Boullata as individuals whose conduct was inequitable. In describing the presentation of the James Declaration to the USPTO, RK Pharma alleges "*Dr. James*, the applicants, and William D. Schmidt were aware that the

[2] In its burying theory, RK Pharma alleges Schmidt filed the IDSs that "intentionally 'buried' one or more highly material prior art references" with "an intent to deceive the [USPTO]." (ECF No. 91 ¶¶ 76, 87–89, 93.) For the cherry-picking theory, RK Pharma alleges Schmidt submitted both the Boullata Declaration and "cherry-picked quotes and intentional mischaracterizations of the prior art" made in the Boullata Declaration as part of his "April 26, 2023 Amendment and Response," and further contends Schmidt did so with "deceptive intent." (*Id.* ¶¶ 111–12.) Finally, RK Pharma adequately alleges "Dr. James, the applicants, and William D. Schmidt were aware that the information provided to the USPTO [in the James Declaration] was not reliable or was misleading as to the conclusions drawn" and acted with "deceptive intent." (*Id.* ¶¶ 143–44.)

[3] The Court presumes RK Pharma's statement that Dr. Boullata "was a consultant and speaker" for ARI sufficiently alleges he was aware he held this relationship; nevertheless, RK Pharma does not allege Dr. Boullata intended to hide this relationship from the USPTO, so he cannot be the "who" for this theory. (ECF No. 91 ¶ 115.) *See also Exergen*, 575 F.3d at 1329.

information provided to the USPTO was not reliable or was misleading as to the conclusions drawn, which were formed in order to obtain allowance of the patent claims that otherwise would not have issued" (ECF No. 91 ¶ 143 (emphasis added)), and that Dr. James "intentionally concocted the incomplete and misleading testing" detailed in his Declaration to deceive the USPTO (*id.* ¶ 142). In laying out its cherry-picking theory, RK Pharma alleges "Dr. Boullata 'cherry picked' selected quotes from the ASPEN guidelines supporting his points[,]" but not their "strong recommendations for new products containing no chromium," and "[t]his selective quoting, while failing to also point out clearly relevant material that does not support the points made, was done with deceptive intent." (*Id.* ¶ 108.) In both cases, Drs. James and Boullata are identified as individuals who knew of an allegedly material misrepresentation and took action to deceive the USPTO. *See, e.g.*, *Depomed*, 2017 WL 2804953 at *6; *IBM*, 2017 WL 1349175 at *9.

Accordingly, the Court will consider the substance of RK Pharma's inequitable conduct claims only as to Schmidt, Dr. Boullata, and Dr. James, and only on the burying, cherry-picking, and misleading data theories. Before doing so, the Court will elucidate the merits requirements of inequitable conduct claims at the pleading stage, which are relevant to the remaining theories.

B. Merits of Inequitable Conduct

In *Therasense, Inc. v. Becton, Dickinson & Co*., 649 F.3d 1276 (Fed. Cir. 2011), the Federal Circuit announced more stringent requirements of materiality and intent for a successful inequitable conduct claim. 649 F.3d at 1288–91. Under this framework, an accused infringer must prove an individual "acted with the specific intent to deceive the PTO" as to material information. *Id.* at 1290. For claims involving nondisclosure or omission of information, this means

demonstrating[4] "the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Id.* The Federal Circuit made clear "[i]ntent and materiality are separate requirements" to be evaluated independently, and courts should neither use a "sliding scale" to supplement a weak showing on one prong with a strong showing on the other nor "infer intent solely from materiality." *Id.*

Following *Therasense*, an inequitable conduct claim must establish the misrepresentation or omission at its heart was but-for material to the patent's issuance, meaning "the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* at 1291; *see also IBM*, 2017 WL 1349175 at *10 (assessing but-for materiality on motion to dismiss); *Jazz Pharms. Ireland Ltd. v. Lupin Inc.*, Civ. A. No. 21-14271, 2025 WL 517856, at *2 (D.N.J. Feb. 18, 2025) ("Pursuant to *Therasense*, the facts must make plausible the inference that, but for the omitted information, the PTO would not have allowed the claims[.]"). As the Federal Circuit intended, this creates a relatively high bar on a motion to dismiss. It is not enough to allege the information would have *impacted* the patentability; rather, the allegations must allow a court to infer the information would have "prevented issuance of the patent." *Inst. for Env't Health*, 2024 WL 5117412 at *9 (finding no inference of but-for materiality in allegations that omitted documents "would be relevant to" patent prosecution). The Federal Circuit has identified one exception to this materiality standard for "affirmative egregious misconduct," such as "the filing of an unmistakably

[4] While *Therasense* espoused a "clear and convincing" burden of proof at trial, *id.*, courts evaluating inequitable conduct claims at the pleading stage have imposed only the Rule 9(b) requirements outlined in *Exergen*, as discussed above, *see, e.g.*, *Diebold Nixdorf*, 2021 WL 861734 at *3 ("Proof by clear and convincing evidence is not required at the pleading stage."); *Fresenius*, 2016 WL 5348866 at *10–11 (noting District of New Jersey courts have applied *Exergen*'s pleading requirements at motion to dismiss post-*Therasense* and Federal Circuit cited *Exergen* in motion to dismiss case after *Therasense*); *Eagle View*, 325 F.R.D. at 94 ("In summary, the heightened merits standard of *Therasense* for proving inequitable conduct is reflected in the heightened standards of pleading inequitable conduct at the motion to dismiss stage.").

false affidavit" or other "extraordinary circumstances" which it considers *per se* material. *Therasense*, 649 F.3d at 1292–93. But claims of omissions, which are not affirmative acts, cannot fit this exception. *See id.*

"Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence." *Id.* The parties debate the degree of evidence required to infer specific intent to deceive at the pleading stage, a "reasonable inference" or the "single most reasonable inference" discussed in *Therasense* post-trial. (ECF No. 104 at 10.) Most courts in this Circuit have concluded a merely reasonable inference is sufficient on a motion to dismiss, relying on the Federal Circuit's language in *Delano Farms Co. v. California Table Grape Commission*, 655 F.3d 1337, 1350 (Fed. Cir. 2011) ("A charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss only if . . . the court may reasonably infer that a specific individual . . . withheld that information with a specific intent to deceive the PTO."); *see also Mycone Dental Supply Co. v. Creative Nail Design, Inc.*, Civ. A. No. 11-4380, 2013 WL 3216145, at *6–7 (D.N.J. June 24, 2013) (recognizing *Therasense* is relevant to pleading requirements at motion to dismiss but agreeing *Delano Farms* shows "reasonable inference" standard preserved and applying it to find intent not alleged); *Taro Pharms. N. Am. Inc. v. Suven Life Scis., Ltd.*, Civ. A. No. 11-2452, 2012 WL 2513523, at *5 (D.N.J. June 28, 2012) (same); *Fresenius*, 2016 WL 5348866 at *10–11 (rejecting "single most reasonable inference" requirement because *Exergen*'s holding general averments of knowledge and intent survive motion to dismiss remained good law); *Eagle View*, 325 F.R.D. at 94 ("A properly pled Rule 12(b)(6) motion of inequitable conduct calls for sufficient and particularized facts that allow the court to reasonably infer the challenged party is liable for intent to deceive the PTO by a material representation / omission.").

Given this consensus, the Court will assess whether RK Pharma alleges a "reasonable inference" of deceptive intent, defined as "one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith." *Exergen*, 575 F.3d at 1329 n.5. To survive a motion to dismiss, therefore, RK Pharma's allegations must be "sufficient to lead a reasonable person to infer that the same individual had the specific intent to deceive the PTO when withholding or misrepresenting the material information, taking into account any objective indications of candor and good faith disclosed in the pleadings and documents referenced therein." *Mycone*, 2013 WL 3216145 at *6. And, in accordance with *Therasense*, "intent to deceive can no longer be inferred from nondisclosure of a reference solely because that reference was known and material; there must be some evidence to prove or support an inference [the] patentee made a deliberate decision to withhold the reference." *iLife Techs. Inc. v. Body Media, Inc.*, Civ. A. No. 14-990, 2015 WL 1000193, at *3 (W.D. Pa. Mar. 6, 2015).

C. Burying Theory

ARI argues the burying theory is deficient in several respects. (ECF No. 102 at 23–32.) First, ARI contends the allegations do not plausibly allege Olson 2019 was "buried" within the '695 Application, since non-OCR files and abstracts are both acceptable under the patent application rules, the specific IDS containing Olson 2019 included only 20 references, and other courts have rejected burying claims when a reference was submitted with many more references. (*Id.* at 23–26.) Second, ARI asserts that, because the patent examiner actually considered Olson 2019 and allowed the claims to issue, the burying cannot be "but-for" material as Federal Circuit law requires. (*Id.* at 26–27 (citing *Therasense*, 649 F.3d at 1291; *Polaris Indus. Inc. v. Arctic Cat Inc.*, Civ. A. No. 14-3412, 2015 WL 4636544, at *5–7 (D. Minn. Aug. 4, 2015); *HTC Corp. v. IPCom GmbH & Co., KG*, 671 F. Supp. 2d 146, 150–51 (D.D.C. 2009); *Sepracor Inc. v. Teva*

Pharms. USA, Inc., Civ. A. No. 09-01302, 2010 WL 2326262, at *7 (D.N.J. June 7, 2010)).) Additionally, ARI contends Olson 2019 "is plainly cumulative of other prior art that was indisputably before the Examiner" (nor did RK Pharma allege Olson 2019 was non-cumulative) and, therefore, cannot be a but-for material cause of patent issuance. (*Id.* at 27–29.) Moreover, ARI contends RK Pharma does not plead any facts indicating the USPTO would have allowed the claim but for Schmidt's actions to bury Olson 2019 because that reference says nothing about reduced silicon impurities, which ARI argues was the key feature on whose basis the patent examiner allowed the claims. (*Id.* at 29–30.) Finally, ARI asserts RK Pharma fails to plead an intent to deceive the USPTO because "affirmative choice to disclose this (cumulative) reference renders implausible any inference of deceptive intent," and RK Pharma's ideas of how ARI could have "unburied" Olson 2019 (such as including relevance statements with references) incorrectly ascribe deceptive intent for "fail[ure] to follow a non-existent rule." (*Id.* at 30–32.)

In response, RK Pharma argues a misrepresentation about the teachings of prior art which leads the examiner to have an "erroneous belief regarding the prior art" and issue the patent is inequitable conduct and but-for material, even when the "art [is] before the examiner." (ECF No. 103 at 14–15 (quoting *Apotex Inc. v. UCB, Inc.*, 763 F.3d 1554, 1361 (Fed. Cir. 2014)).) RK Pharma contends Schmidt misrepresented "the state of the art" regarding added chromium in multi-trace element products, and "the lack of added chromium in [multi-trace element] products" discussed in prior art "is an express reason for allowance" Schmidt knew to be inaccurate. (*Id.* (citing *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1353–54 (Fed. Cir. 2021); *Luv n' Care, Ltd. v. Laurain*, 98 F.4th 1081, 1097 (Fed. Cir. 2024)).) Further, RK Pharma disagrees this Court can accept ARI's assertions that Olson 2019 was actually considered by the patent examiner and was cumulative of other art on a motion to dismiss because these are both questions of fact. (*Id.* at 15–

17.) RK Pharma argues it alleged "Olson 2019 contradicts the Examiner's reason for allowance, which indicates that the Examiner did not consider Olson 2019," so materiality was adequately pled, and determining cumulativeness will require expert testimony. (*Id.* at 16–17.) RK Pharma also contends the patent examiner allowed the claims following review of the "amendments and arguments made in the April 26, 2023," where the alleged "misrepresentations were made" that Olson 2019 contradicts.[5] (*Id.* at 17.) Lastly, RK Pharma argues it sufficiently alleged facts to create a "reasonable inference" of deceptive intent by Schmidt because he submitted Olson 2019 knowing the issue of chromium was important for patentability, conducted three interviews with the patent examiner where those concerns would have been elicited, argued around certain references relevant to the chromium issue without referencing Olson 2019, and "solicited and submitted" the Boullata and James Declarations and their alleged misstatements on this issue. (*Id.* at 18.)

ARI's reply reiterates its view that RK Pharma fails to plead but-for materiality and intent and contends RK Pharma misinterprets the pleading requirements for both on a motion to dismiss. (ECF No. 104 at 6–10.) In response to RK Pharma's contention that whether the patent examiner reviewed Olson 2019 is a question of fact, ARI points to annotations in the prosecution history indicating the examiner reviewed all references in the relevant IDS except those crossed out, and Olson 2019 was not struck through, concluding this "is fatal to RK Pharma's burying theory." (*Id.* at 7.) ARI distinguishes RK Pharma's cited authority as pertaining to allegations of affirmative egregious misconduct and demonstrably false statements, both of which ARI asserts were not pled in the counterclaims and cannot be added through the opposition brief. (*Id.* at 8.) ARI also rejects

[5] Additionally, RK Pharma claims three statements made in the April 26, 2023 submissions "constituted affirmative egregious misconduct" because they were false, which renders them "*per se* material." (ECF No. 103 at 17–18 (citing *Therasense*, 649 F.3d at 1292; *Luv n' Care*, 98 F.4th at 1097).)

RK Pharma's position that cumulativeness cannot be evaluated on a motion to dismiss, explaining that "courts routinely dismiss inequitable conduct claims . . . if the pleadings and material incorporated by reference (for example, the file history) show that the allegedly withheld material is cumulative." (*Id.* at 8–9.) Further, ARI contends RK Pharma's recounting of the prosecuting history demonstrate the patent examiner "was aware of relevant art, including as it relates to chromium levels" and that "the subject matter RK Pharma now alleges was withheld was squarely before the Examiner" through other references. (*Id.* at 9.) Regarding intent, ARI reiterates the disclosure of Olson 2019 to the patent examiner precludes an inference of deceptive intent pursuant to *Therasense*. (*Id.* at 10.)

ARI's main argument against materiality for the burying theory is that the patent examiner "actually considered" Olson 2019. (ECF No. 102 at 26.) RK Pharma argues the Court cannot assess this at the pleading stage.[6] (ECF No. 103 at 15–16.) The Court agrees with ARI. ARI cites several cases where courts looked at evidence from the file history indicating the examiner considered the prior art to assess materiality on a motion to dismiss, *Polaris*, 2015 WL 4636544 at *5–7 (finding patents and prosecution history "reflect that the patent examiner did consider each of the four references" in dispute); *Sepracor*, 2010 WL 2326262 at *7 ("The second reason Wockhardt's inequitable conduct claim must be dismissed is because the oral toxicity study results were before the examiner, and he was entitled to reach his own conclusions on the study."); *HTC Corp.*, 671 F.

[6] Neither side contests the file history of the '695 Application, attached as exhibits to the Motion, is incorporated into RK Pharma's counterclaims such that its contents may be considered by the Court without converting the Motion to one for summary judgment. *See In re Burlington*, 114 F.3d at 1426; *Mycone*, 2013 WL 3216145 at *7 n.9 (finding district court could refer to patent application because it was integral to inequitable conduct counterclaims); *Par Pharm., Inc. v. Luitpold Pharms., Inc.*, Civ. A. No. 16-02290, 2017 WL 452003, at *4 (D.N.J. Feb. 2, 2017) ("In a Hatch-Waxman action such as this, the Court may consider the file histories of the Patents-in-Suit.").

Supp. 2d at 150–51 (determining no materiality where USPTO had reviewed reference and found it cumulative), while RK Pharma provides no authority for its position (ECF No. 103 at 15–16). The Court has also identified additional authority in support of this view.[7] Further, the '695 Application's file history is incorporated in the counterclaim allegations, meaning the Court may consider its substance. *See Par Pharm.*, 2017 WL 452003 at *4.

Reading the counterclaims with the incorporated '695 Application in the light most favorable to RK Pharma, any "burying" of Olson 2019 was not but-for material as alleged because the patent examiner explicitly considered it. The facts here are highly analogous to those in *Polaris*, where counterclaimants alleged material references were buried in the applicants' IDSs. *Polaris*, 2015 WL 4636544 at *5–7. Looking at the prosecution history and related documents, the court there found "the public record of the '028 Patent prosecution" showed "[t]he examiner either signed or initialed that he had considered each of the relevant prior art references during prosecution of the patent," and they could not be material as a result. *Id.* at *7. Here, the patent examiner explicitly stated "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH" on a copy of the IDS containing Olson 2019, and that reference is not lined through. (ECF No. 102-15 at 4.) Since, "[a]bsent proof to the contrary, we assume that the examiner did consider the references," *Molins*, 48 F.3d at 1184, this notation shows the patents-in-suit issued in

[7] *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) (reversing judgment for clear error where examiner initialed references considered and "stated that he had considered all of the cited prior art," and noting "[a]bsent proof to the contrary, we assume that the examiner did consider the references"); *Ill. Tool Works Inc. v. Termax LLC*, Civ. A. No. 20-5416, 2023 WL 4707263, at *8 (N.D. Ill. July 24, 2023) (finding patent examiner did consider cited references, despite alleged burying, even though examiner made no note of reasons for allowance).

spite of Olson 2019's allegedly contradictory findings. Accordingly, RK Pharma has failed to plead Schmidt's actions around Olson 2019 were but-for material to their issuance.[8]

While it is possible RK Pharma adequately pled deceptive intent,[9] given the Court's finding any burying of Olson 2019 was not but-for material, the Court need not address this element.

D. Cherry-Picking Theory

ARI also contends RK Pharma's cherry-picking theory—that the Boullata Declaration selectively quoted the ASPEN Guidelines to intentionally obscure a "strong recommendation for new productions containing no chromium" from the examiner—lacks sufficient allegations of materiality and intent. (ECF No. 102 at 32–36 (quoting ECF No. 91 ¶ 106).) As to materiality, ARI argues the ASPEN Guidelines "were before the Examiner[,] which fulfilled ARI's duty of disclosure," and the patent examiner was free to accept or reject any further arguments made as to the ASPEN Guidelines' import as attorney or patentee arguments. (*Id.* at 33 (citing *Catalyst*, ECF

[8] In its opposition, RK Pharma asserts three statements made in the April 26, 2023 submissions "constituted affirmative egregious misconduct," which renders them "*per se* material." *See supra*; (ECF No. 103 at 17–18.) As ARI notes, the counterclaims contain no allegations of egregious misconduct based on these statements, so the Court is loath to consider them. *See Mills v. Ethicon, Inc.*, 406 F. Supp. 3d 363, 287 (D.N.J. 2019). But even if the Court were to read the allegations (which incorporate the prosecution history) to encompass these statements, the Court finds there are insufficient allegations these statements are "unmistakably false" to survive a motion to dismiss. *See Therasense*, 649 F.3d at 1292–93.

[9] "Allegations that an applicant buried a material reference with deceptive intent may give rise to a viable inequitable-conduct claim." *Ill. Tool Works*, 2023 WL 4707263 at *7. However, the dynamics of patent infringement litigation—where alleged infringers often respond with inequitable conduct claims—may lead patent prosecutors to overwhelm the USPTO with references in an effort to guard against such accusations. *See KPR U.S., LLC v. LifeSync Corp.*, Civ. A. No. 22-60468, 2023 WL 5529176, at *7 (S.D. Fla. Aug. 27, 2023) (citing *Therasense*, 649 F.3d at 1289). "Thus, 'burying' is really nothing more than a species of the Rule 9(b) intent standard, which requires specific facts supporting an inference of an intent to deceive." *Nomadix, Inc. v. Hosp. Core Servs. LLC*, Civ. A. No. 14-08256, 2015 WL 3948804, at *9 (C.D. Cal. June 29, 2015) (determining "multiple overlapping and cross-referenced applications, some of which may have omitted a key reference . . . , and which (Defendant alleges) are overstuffed with irrelevant references" reasonably resulted in "an inference of bad faith—i.e., an intent to deceive").

No. 121 at 12; *Kawasaki Jukogyo Kabushiki Kaisha v. Rorze Corp.*, Civ. A. No. 22-04947, ECF No. 144 (N.D. Cal. Jun. 14, 2024)).) Characterizing this as "settled law," ARI asserts that "patentee arguments about art before the Examiner" cannot be but-for material because the USPTO conducts its own evaluation of the art itself. (*Id.* (citing *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007); *Horizon Glob. Ams., Inc. v. N. Stamping, Inc.*, Civ. A. No. 1:20-00310, 2021 WL 2952807, *4–5 (N.D. Ohio July 14, 2021)).) Therefore, ARI argues "RK Pharma's belief that Dr. Boullata incorrectly characterized the ASPEN guidelines is legally irrelevant" because the ASPEN Guidelines were in front of the examiner, ARI made reference to its chromium recommendations, and "the PTO considered them and allowed the claims." (*Id.* at 33–34 (citing *Avery Dennison Corp. v. Cont'l Datalabel, Inc.*, Civ. A. No. 10-2744, 2010 WL 4932666, at *3–4 (N.D. Ill. Nov. 30, 2010)).) Additionally, ARI asserts RK Pharma's allegations show the ASPEN Guidelines were cumulative of another prior art reference cited by the patent examiner, Burjonrappa, and cannot be material as a result. (*Id.* at 34–35.) ARI also contends the disclosure of the ASPEN Guidelines to the USPTO renders "any inference that anyone associated with the prosecution intended to deceive the Examiner about the references' contents" not plausible. (*Id.* at 35–36 (citing *Allergan USA, Inc. v. Prollenium US Inc.*, Civ. A. No. 19-126, 2019 WL 7298569, at *8 (D. Del. Dec. 30, 2019)).)

RK Pharma argues "Dr. Boullata's misleading and deceptive statements in his Declaration [are] indisputably material." (ECF No. 103 at 18.) RK Pharma contends the Boullata Declaration's recounting of multi-trace element product development "conveniently stopped at 2015, right when ASPEN began recommending reducing or removing chromium[.]" (*Id.* at 18–19.) As a result, RK Pharma asserts the complaint and integrated prosecution history sufficiently allege Dr. Boullata "presented the misleading conclusion that there was a 'consensus'" in the prior art to add chromium to multi-trace element formulations, "echoed by [Schmidt]." (*Id.* at 19.) For the first

time, RK Pharma contends "Dr. Boullata also discussed Burjonrappa's 'incompatibility' with the Drugs.com disclosures but did not mention Olson 2019," evidencing a deliberate choice to "[keep] silent about Olson 2019's teachings" on chromium. (*Id.*) By presenting the prior art in this manner, RK Pharma argues Dr. Boullata and Schmidt told the USPTO "there was a long-felt but unmet need" for reduced chromium in multi-trace element formulations, "even though Olson 2019 and other art had already disclosed the solution to such [an] 'unmet' need." (*Id.*) Pointing to a portion of the file history where the patent examiner withdrew obviousness rejections "in view of the amendments to the claims and Applicant's arguments," RK Pharma concludes this is sufficient to allege that, "[h]ad the deceptive statements not been made, the examiner would not have allowed the claims." (*Id.* at 19–20.) In response to ARI's contention the statements at issue are attorney argument, RK Pharma asserts the counterclaims allege Dr. Boullata made these statements as the "technical expert declarant" and Schmidt merely "repeated" and "submitted" them. (*Id.* at 20.) Further, RK Pharma contends Dr. Boullata and Schmidt's intent "can be inferred from the deceptiveness of the [Boullata] declaration," which stopped its analysis at 2015, despite being submitted in 2023, and both individuals' knowledge "the state of the art had evolved" between 2015 and the effective filing date of 2020. (*Id.*)

In reply, ARI reaffirms its view the complained-of statements are "mere legal or interpretive arguments favoring patentability" and, as a matter of law, cannot be misrepresentations unless they "contain gross mischaracterizations or unreasonable interpretations" or are "demonstrably false." (ECF No. 104 at 10–11 (quoting *Catalyst*, ECF No. 121 at 12).) ARI also asks the Court to disregard RK Pharma's arguments "regarding Burjonrappa's incompatibility with the Drugs.com disclosures and whether there was a long-felt but unmet need of not adding or

supplementing chromium," as these arguments are absent from the counterclaims. (*Id.* at 11 n.2 (citing *Mills*, 406 F. Supp. 3d at 287).)

When it comes to materiality, Federal Circuit precedent distinguishes statements in affidavits from arguments for patentability made to the patent examiner. *Compare Young*, 492 F.3d at 1349 (reversing finding applicants' statements to USPTO about prior art were material misstatements because they were "attorney argument[] attempting to distinguish the claims from the prior art, not gross mischaracterizations or unreasonable interpretations"), *with Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983) ("In contrast to cases where allegations of fraud are based on the withholding of prior art, there is no room to argue that submission of false affidavits is not material."), *and Therasense*, 649 F.3d at 1292 (remarking "the filing of an unmistakably false affidavit" is material, "affirmative act[] of egregious misconduct"). While an attorney "is free to argue vigorously in favor of patentability without being subject to allegations of inequitable conduct," she can still cross the line if the advocacy contains "genuine misrepresentations of material fact." *Ring Plus, Inc. v. Cingular Wireless Corp.*, 614 F.3d 1354, 1360–61 (Fed. Cir. 2010) (quoting *Rothman v. Target Corp.*, 556 F.3d 1310, 1328 (Fed. Cir. 2009)).

But if "an applicant's alleged misrepresentations consist solely of arguments to the Examiner that are not unreasonable interpretations or demonstrably false," they cannot support an inequitable conduct claim. *Wyeth Holdings Corp. v. Sandoz, Inc.*, Civ. A. No. 09-955, 2012 WL 600715, at *10 (D. Del. Feb. 3, 2012), *report and recommendation adopted*, Civ. A. No. 09-955, 2012 WL 749378 (D. Del. Mar. 1, 2012). As a court in this District described in *Warner Chilcott*:

> Two important points arise from the Federal Circuit's finding [in *Young*]. First, the Federal Circuit drew a line between a reasonable attempt to distinguish the art and statements that evidence a certain level of culpability: statements that are demonstrably false, gross mischaracterization, or unreasonable interpretations. Second, where

> the examiner has the prior art references, he is free to reject the statements made by an applicant as argument.

2013 WL 6627694 at *8 (denying leave to amend with inequitable conduct counterclaims because counterclaimants "allege[d] only that 'a person of ordinary skill in the art would not have interpreted the prior art in the way the applicants portrayed it to the examiner,'" examiner had prior art references, and applicant responded to initial rejection "by summarizing and quoting" prior art); *see also Catalyst Pharms., Inc. v. Jacobus Pharms. Co., Inc.*, Civ. A. No. 20-14590, 2022 WL 22897850, at *6 (D.N.J. May 26, 2022) ("[I]t is settled law that attorney argument about a reference the Patent Office *actually considered* cannot give rise to a claim of inequitable conduct." (citing *Scripps Clinic & Rsch. Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991))).

In contrast, if a declaration or affidavit submitted in support of a patent application allegedly contains misrepresentations on which the patent examiner relied to allow the patent to issue, this is but-for material. *See, e.g.*, *Allergan USA*, 2019 WL 7298569 at *7 (finding expert declaration was but-for material to allowance because "[t]he examiner's description of the applicant's understanding of the state of the art at the time of the invention corresponds with the representations in Dr. Lebreton's declaration"); *Wyeth*, 2012 WL 600715 at *12 (finding allegations of misrepresentation material where employee declaration mischaracterized prior art's teachings and omitted information about applicant's "internal testing procedures and protocols").

Viewing the allegations in the light most favorable to RK Pharma, they fail to allege Schmidt's statements crossed the line from vigorous argument to misrepresentation and were therefore material. *See Ring Plus*, 614 F.3d at 1360–61. RK Pharma alleges Schmidt "makes the same cherry-picked quotes and intentional mischaracterizations of the prior art that the Boullata Declaration makes." (ECF No. 91 ¶ 111.) First, "cherry-picked quotes" alone cannot be the basis of a material misrepresentation in an attorney's presentation to the USPTO, especially when the

references at issue were actually considered by the patent examiner. *See Catalyst Pharms.*, 2022 WL 22897850 at *6; *Warner Chilcott*, 2013 WL 6627694 at *8. And while RK Pharma alleges Schmidt's statements were "intentional mischaracterizations" mirroring Dr. Boullata's, it fails to allege Schmidt made statements about the ASPEN Guidelines that were "unreasonable interpretations or demonstrably false." *Wyeth*, 2012 WL 600715 at *10. Instead, RK Pharma alleges the ASPEN Guidelines "contain strong recommendations for new products containing no chromium," in that ASPEN 2015 "recommend[s] that chromium 10 mcg is sufficient for most patients," and "ASPEN 2012 recommends that in addition to the current multiple [trace element] products that contain 10–15 mcg/d of chromium, a multiple [trace element] product without added chromium should be made and that chromium contaminates in [parenteral nutrition] products satisfies the requirements, and therefore, additional supplementation is unnecessary." (ECF No. 91 ¶¶ 108–10.) At best, these allegations indicate conflicting recommendations between the two ASPEN Guidelines: in 2012, the recommendation indicated there was effectively a product with no chromium, and in 2015, that "most patients" could have 10 mcg of chromium. (*Id.*) Therefore, it was not unreasonable or clearly false for Schmidt to advocate a particular interpretation to the patent examiner. *See Young*, 492 F.3d at 1349.

While the standard of analysis for Dr. Boullata is slightly different, the result is the same: as pled, the allegations regarding the ASPEN Guidelines do not present a clear picture of what was recommended, so Dr. Boullata's presentation cannot be a material misrepresentation. *See Allergan*, 2019 WL 7298569 at *7. Nor does RK Pharma adequately allege the Boullata Declaration was the reason the patent examiner withdrew the obviousness rejections. While RK Pharma conclusorily claims "but for [Schmidt's] mischaracterization of the references in the Boullata Declaration, no claim of the '548 patent would have been allowed and issued" (ECF No. 91 ¶ 114), it does not

allege a clear connection between the Boullata Declaration and the patent examiner's decision. Indeed, the language of the statement of allowance it cites in opposition says merely the objections were withdrawn "in view of the amendments to the claims *and Applicant's arguments*," without indicating which arguments were persuasive.[10] (ECF No. 103 at 20 (emphasis added)); *contra Allergan*, 2019 WL 7298569 at *7 (finding expert declaration was but-for material to allowance because "[t]he examiner's description of the applicant's understanding of the state of the art at the time of the invention corresponds with the representations in Dr. Lebreton's declaration").

As pled, the allegations fail to state a but-for material misrepresentation in the Boullata Declaration or Schmidt's submissions. The Court therefore will not address the parties' arguments on deceptive intent as to this theory.

E. Misleading Data Theory

Finally, ARI asserts RK Pharma's misleading data theory does not meet the motion to dismiss standard because "RK Pharma does not even pretend to identify a false statement" in the James Declaration. (ECF No. 102 at 39.) ARI argues RK Pharma's allegations that the comparative testing data Dr. James provided was "scientifically unsound" and methodologically flawed "merely disput[e] the merits of Dr. James' analysis" because it alleges only it is not clear Dr. James conducted replication studies on multiple samples or calculated a standard error if there were replicates. (*Id.* at 38–39.) Therefore, ARI contends RK Pharma fails to allege the James Declaration contains "demonstrably false" misrepresentations because "[q]uestioning the soundness of a scientific conclusion is not the same as identifying a falsehood." (*Id.* at 39 (quoting

[10] While RK Pharma also gestures in its opposition at the Drugs.com and Olson 2019 references as contradicting the ASPEN Guidelines and contends the Boullata Declaration and Schmidt statements misdirected the patent examiner as to their significance, these allegations are absent from the counterclaims, and the Court will not consider them as a result. *See Mills*, 406 F. Supp. 3d at 287.

Catalyst, Civ. A. No. 20-14590, ECF No. 121 at 12; citing *Kawasaki Jukogyo*, Civ. A. No. 22-04947, ECF No. 144).) Moreover, ARI argues the James Declaration's "detailed experimental protocols and data" were arguments for patentability before the patent examiner, who could make his own assessment of whether to rely on them. (*Id.* at 40 (citing *Young*, 492 F.3d at 1349; *WesternGeco L.L.C. v. ION Geophysical Corp.*, Civ. A. No. 4:09-1827, 2012 WL 567430, at *20 (S.D. Tex. Feb. 12, 2012)).) As with the cherry-picking theory, ARI also contends the fact Schmidt and Dr. James presented Dr. James' methodology and the results in the James Declaration to the patent examiner means there cannot be a plausible inference of deceptive intent. (*Id.* (citing *Horizon Glob.*, 2021 WL 2952807, at *4–5).)

RK Pharma refutes ARI's view the testing data contained in the James Declaration constituted "a legal or interpretative argument favoring patentability" because it contends its "allegations regarding the misrepresentations in the James Declaration are all factual," and the counterclaims allege the data reported there in is '"unreliable' and 'unlikely,' as a matter of fact." (ECF No. 103 at 23–24.) Accordingly, RK Pharma argues its disagreements with ARI about whether the results Dr. James described were unlikely or unreliable are disputes of fact that may not be resolved on a motion to dismiss. (*Id.* at 24.) Further, RK Pharma asserts "[t]he submission of incomplete or unreliable testing data to the patent office can constitute an especially egregious form of inequitable conduct because data . . . are there to prove a point and presumed material." (*Id.* (citing *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 176 F. App'x 117 (Fed. Cir. 2006); *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 (Fed. Cir. 2003)).) RK Pharma contends the patent examiner "asked the applicants . . . for facts to show secondary considerations such as 'unexpected results,'" and ARI prepared the James Declaration's "unreliable, unlikely, and misleading testing data and information" "despite knowing" the patent examiner could not verify

it and would wish to rely upon it. (*Id.* at 25.) And RK Pharma claims "[a]t least one court in this District has held that allegations of an improper comparison of testing data, and misleading presentations of testing details or characterization of the samples tested" can meet the motion to dismiss pleading standard. (*Id.* (citing *Fresenius*, 2016 WL 5348866 at *11).)

ARI counters that, while RK Pharma's opposition claims the James Declaration contains false testing data, "the counterclaims never allege that any of the data Dr. James presented is actually false." (ECF No. 104 at 13.) Rather, ARI contends the counterclaims only allege Dr. James used "scientifically unsound reasoning," which does not amount to an allegation Dr. James "made a demonstrably false statement of fact." (*Id.* at 13–14.) ARI also argues RK Pharma's cited cases are inapposite because they "involved specific deceptive acts by the patentee," such as withholding information about the testing circumstances, making affirmative misrepresentations about testing, or making the deliberate choice to comparison test the stability feature at "the heart of the patent" against products the patentee knew were less stable than its own prior product. (*Id.* at 14–15 (citing *Aventis*, 176 F. App'x at 118, 123; *Hoffman-La Roche*, 323 F.3d 1367–68; *Fresenius*, 2016 WL 5348866 at *11).) In contrast, ARI argues RK Pharma "has not alleged that Dr. James knew his conclusions were wrong and provided them to the Examiner anyway; instead, RK Pharma disagrees with the conclusions," and this is insufficient to survive a motion to dismiss. (*Id.* at 15.)

Viewed in the most favorable light, RK Pharma alleges the James Declaration made a misrepresentation of material fact that was a but-for cause of the patent examiner's decision to issue the patents-in-suit. The Court finds the District of Delaware's decision in *Wyeth* to be factually analogous and instructive. 2012 WL 600715 at *10. There, the counterclaimants alleged the applicant's representatives prepared a declaration containing "flawed" data showing unexpected results. *Id.* at *9–10. The counterclaimants also allege the declarant failed to disclose

"Wyeth's internal testing procedures," as well as "significant error rates" associated with the data. *Id.* at *12. Based on these allegations, as well as the fact that the patent examiner specifically cited the data "as the primary reason for his allowance of the patent," the Court found there was a reasonable inference of but-for materiality, and the representations in the declaration and related statements to the USPTO could not be dismissed as attorney advocacy. *Id.* at *10–12.

Here, RK Pharma alleges a similar series of events as in *Wyeth*. RK Pharma alleges that, at a January 19, 2023 interview with the applicants, the patent examiner discussed ARI "providing evidence and/or affidavits showing secondary consideration" that the absence of chromium and the resultant concentrations "are not simply routine optimizations of multi[-]trace element formulation." (ECF No. 91 ¶ 73.) The James Declaration was submitted following that conversation. (*Id.* ¶ 74.) RK Pharma alleges the comparison testing in it was "unreliable" because a single comparison test between samples could not definitively demonstrate ARI's formulation produced higher levels of silicon, and the James Declaration did not indicate how many tests were done and what the standard error was, if any. (*Id.* ¶¶ 133–41.) RK Pharma also alleges the patents-in-suit would not have issued "but for . . . Schmidt's intentionally incomplete analysis and testing to draw the conclusions in the James Declaration." (*Id.* ¶ 146.) Further, the patent examiner's reason for allowance explicitly credits ARI's "showing of *unexpected data*, wherein the absence of chromium in a trace element composition results in a composition having considerably less silicon impurities when compared to a trace element composition comprising chromium" (ECF No. 102-13 at 4 (emphasis added)). The data referenced by the patent examiner is clearly the data in the James Declaration and was therefore but-for material. *See Wyeth*, 2012 WL 600715 at *10; *Allergan*, 2019 WL 7298569 at *7.

While ARI argues RK Pharma's allegations amount to "technical criticisms" of the methodology Dr. James used (ECF No. 104 at 14), courts have allowed inequitable conduct claims to proceed where, as here, the patentee allegedly failed to disclose information that would have changed the patent examiner's view of submitted data on which the examiner then relied, *see Wyeth*, 2012 WL 600715 at *12; *Invista*, 2013 WL 12304544 at *6–9 (finding but-for materiality alleged where, among other things, applicants "failed to disclose the standard deviations associated with disclosed averages" and "internal test data" on testing supporting applicants' "unexpected results" argument, and "there are facts pled suggesting that the merits of this argument were significant to the Examiner's ultimate decision"); *Fresenius*, 2016 WL 5348866 at *11 (determining comparison testing against formulations applicants knew were inferior to grandfathered product without disclosing knowledge stated claim at motion to dismiss stage). Accepting RK Pharma's allegations as true, Dr. James and Schmidt presented "unfounded" and "misleading" test results that were the primary reason the patent examiner issued the patents-in-suit, which is sufficient at this stage in the litigation. *See Invista*, 2013 WL 12304544 at *9 ("Although [patentees] dispute how specifically related some of these facts were to the Examiner's ultimate acceptance of the . . . argument (and thus, the Examiner's decision on patentability), that dispute is one not meant to be resolved at the pleading stage.").

RK Pharma has also alleged facts creating a reasonable inference Dr. James and Schmidt acted with deceptive intent. *See Delano Farms*, 655 F.3d at 1350; *Fresenius*, 2016 WL 5348866 at *10–11; *Wyeth*, 2012 WL 600715 at *13. Again, *Wyeth* is instructive. There, the declarant was an employee of the applicant familiar with the testing processes and who allegedly knew about the problems with the data "but made a calculated, deliberate decision to conceal it in his presentations to the Examiner." *Id.* The court found these allegations gave rise to a "plausible inference" the

declarant acted with deceptive intent, especially "[g]iven [his] experience, his direct oversight of this process, and his statements to the Examiner." *Id.* at 14. Here, RK Pharma asserts Dr. James and Schmidt "were aware that the information provided to the USPTO was not reliable or was misleading as to the conclusions drawn, which were formed in order to obtain allowance of the patent claims." (ECF No. 91 ¶ 143.) The information contained in the James Declaration indicates he was an employee of ARI with significant technical experience and helped conduct the comparative test of Multrys and Tralement with the competitor products. (ECF No. 102-12 ¶¶ 1–3 (describing Dr. James' role and qualifications), ¶ 18 ("As discussed below and in Table E, *we conducted* head to head comparative tests to determine levels of elemental impurities[.]" (emphasis added)).) And RK Pharma alleges Dr. James and Schmidt knew the patent examiner would believe "the information in the James Declaration was unbiased [and] truthful" because Dr. James "would not want to perjure himself." (ECF No. 91 ¶ 144.) Together, the alleged facts allow the Court to reasonably infer the James Declaration was prepared by Dr. James and submitted by Schmidt with deceptive intent. *See Wyeth*, 2012 WL 600715 at *13–14.

Accordingly, all RK Pharma's inequitable conduct theories except for the misleading data theory are dismissed.

F. Striking Affirmative Defenses

ARI asks this Court to strike the corresponding inequitable conduct affirmative defenses for those inequitable conduct claims that were dismissed. (ECF No. 102 at 4, 41.) RK Pharma does not oppose striking those defenses corresponding with dismissed claims. (ECF No. 103.)

Federal Rule of Civil Procedure 12(f) permits the court to strike "an insufficient defense." Though striking pleadings is highly disfavored, *see Garlanger*, 223 F. Supp. 2d at 609, courts have recognized inequitable conduct claims and affirmative defenses "rise or fall together," and where

the former are dismissed, striking the latter is appropriate, *see Senju*, 921 F. Supp. at 306; *Depomed*, 2017 WL 2804953, at *9 (striking affirmative defenses corresponding with dismissed theories of inequitable conduct).

Having dismissed all RK Pharma's inequitable conduct theories except for the misleading data theory, the Court will therefore strike RK Pharma's Seventh Additional Defense of Inequitable Conduct except as to the misleading data theory.

IV. CONCLUSION

For the reasons set forth above, and for good cause having been shown, ARI's Motion to Dismiss and to Strike (ECF No. 102) is **GRANTED IN PART AND DENIED IN PART**. Specifically, RK Pharma's inequitable conduct claims premised on the burying, cherry-picking, and undisclosed relationship theories are dismissed and the related affirmative defenses stricken. RK Pharma has stated a claim of inequitable conduct as to its misleading data theory by Dr. James and Schmidt and may proceed with its claim and the associated defense on that basis. An appropriate order follows.

Dated: August 12, 2025

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE